

PSJ19 Walmart Opp Exh 9 – WMT_MDL_000011107-11109

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Pharmacy Manual



Evaluating Orders of Interest and Suspicious Order Reporting

Purpose

DEA regulations require distributors of controlled substances to have a system in place designed to identify suspicious orders. The following procedure will be followed by Walmart to evaluate Orders of Interest and to report Suspicious Orders to the appropriate federal and state agencies.

Definitions

Order of Interest – An order that warrants follow-up evaluation to determine whether it is suspicious.

Suspicious Order – An Order of Interest which has been evaluated and determined to be suspicious. Suspicious Orders may include, but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern and orders of unusual frequency.

Appropriate Order – An Order of Interest which has been evaluated and determined not to be a Suspicious Order.

Procedures

Evaluating an Order of Interest

All drug orders submitted to a Walmart Pharmacy Distribution Center will be monitored and Orders of Interest will be identified and evaluated. All reported Orders of Interest will be evaluated according to the procedures below and the results of the evaluation may be presented to the Health & Wellness Director of Controlled Substances and the Sr. Director of Pharmacy Logistics, or a designated representative of each, for further evaluation to determine whether the Order of Interest is a Suspicious Order. The Health & Wellness Compliance Advisory Panel will provide high level oversight of the evaluation process.

Order of Interest initial inquiries will be conducted by the Pharmacy Logistics Compliance team. The initial inquiry into an Orders of Interest may involve Global Investigations, Practice Compliance, Pharmacy Logistics Compliance, DC associates involved in the monitoring process, and Store/Club associates involved in placing the Order of Interest.

Every Order of Interest will be thoroughly evaluated by the Logistics Compliance team. Orders of Interest, once evaluated and verified as appropriate, will be processed and shipped as ordered. If an Order of Interest is not resolved within 4 business days, the Pharmacy Logistics Compliance team will submit documentation related to the outstanding Order of Interest to the Health & Wellness Director of Controlled Substances and the Sr. Director of Pharmacy Logistics, or a designated representative of each, for further evaluation.

The determination of whether an Order of Interest is a Suspicious Order will be made by agreement of the Health & Wellness Director of Controlled Substances and the Sr. Director of Pharmacy Logistics. In the event that either party is unavailable, the determination may be made by delegate(s) approved by the Controlled Substance Advisory Panel.

The Health & Wellness Director of Controlled Substances and the Sr. Director of Pharmacy Logistics, or their delegate(s), will have no longer than two business days to determine if the Order of Interest is an Appropriate or Suspicious Order. If the parties cannot reach an agreement within this time frame, the Controlled Substance Advisory Panel, or a representative subset of the same, will make the determination.

A store whose order is identified as an Order of Interest and held beyond the expected shipment date will be notified of the shipment delay as quickly as possible.

While each situation requires an individualized approach, below are general guidelines that may be used to evaluate Orders of Interest. Additional guidelines may be available in Pharmacy Logistics and Health & Wellness Practice Compliance procedures.

Initial Inquiry

The Order of Interest should be evaluated to identify the unusual characteristics of the order. Evaluation of the unusual characteristics will assist in making the determination whether or not the Order of Interest is a Suspicious Order.

Unusual characteristics may include:

- Unusual frequency
- Unusual size
- Unusual pattern

Review Prior Orders

The prior order history for the store/club in addition to Item Combinations should be reviewed. This review may include, but should not be limited to the following:

- Whether this store/club has been the subject of an Order of Interest evaluation in the past.
- Overall trending for the item(s) involved in the evaluation.
- Any unusual ordering activity in the past.
- Overall percentages of Controlled Substances relative to other prescription products, and any recent changes.
- Changes to the physical environment of the store/club, such as a new medical practice opened in their area.
- Changes in drug availability. (Manufacturer out-of-stock issues.)

Interview Store/Club Associates

Associates involved in placing the Order of Interest may be asked to explain the unusual characteristics of the order.

Verify Information Provided by Store/Club Associates

Information provided by store/club associates to explain the unusual characteristics of the order should be verified. For example, if the associate stated that the demand for additional product is a result of a new medical practice in their area, the existence of the practice and the specialty of the new medical practice should be verified.

Documentation and Review

All Order of Interest evaluations must be documented.

Suspicious Order Reporting

If it has been determined, after evaluation, that an Order of Interest is a Suspicious Order, the following process will be followed to report the Suspicious Order to key stakeholders, to the Drug Enforcement Administration (DEA) and necessary state agencies, as required by law.

- The Health & Wellness Director of Controlled Substances ("Director") will provide a "Memo of Determination of Suspicious Order" to the following stakeholders:
 - Walmart Health & Wellness Practice Compliance
 - Walmart Health & Wellness Legal
 - Walmart Global Investigations
 - Walmart Logistics Compliance
 - Walmart Logistics Legal

- Walmart Pharmacy Operations
 - Servicing Warehouse General Manager
- The Health & Wellness Director of Controlled will report all Suspicious Orders to the DEA and necessary state agencies, as required by law, within one business day of the determination. The report will be made on the Suspicious Order Regulatory Reporting Form, as approved by Health & Wellness Legal. A remediation plan, if appropriate, may be included in the report.

Role of Health & Wellness Director of Controlled Substances and the Health & Wellness Advisory Panel

The Health & Wellness Advisory Panel ("Panel") will be responsible for providing high level oversight of the evaluation process. A summary of all Order of Interest evaluations and all actions taken by the Health & Wellness Director of Controlled Substances ("Director"), including the reports submitted to federal and necessary state agencies will be presented to the Panel by the Director on a routine basis as established by the Panel. The Director, in consultation with the Advisory Panel and Logistics Operations, may provide a remediation plan to the servicing warehouse; field management and pharmacy staffs after Orders of Interest have been evaluated. An Order of Interest evaluation, whether or not determined to be a Suspicious Order may lead to additional oversight of the subject pharmacy. Additional oversight may include, but is not limited to, a lower order threshold on one or more items, more frequent evaluation of orders, or blocks being placed on specific drugs.

Communication and Documentation Retention

All forms of communication, both internal and external, must be retained. The following guidance should be followed when communicating to ensure proper document retention:

- Telephone and in-person communication should be reduced to written documentation.
- Written communication sent by common carrier must have a delivery confirmation attached to a copy of the document which was sent.
- E-mail and fax communication should be retained electronically along with email or fax confirmation of delivery.

All documentation related to Order of Interest evaluations, determination of Suspicious Orders, and federal and state reporting must be retained for three years.